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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,967	05/04/2001	Emanuel Calenoff	21417/92378	6936
23644	7590	02/08/2005	EXAMINER	
BARNES & THORNBURG			CHEU, CHANGHWA J	
P.O. BOX 2786			ART UNIT	
CHICAGO, IL 60690-2786			PAPER NUMBER	

1641

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/848,967

**Applicant(s)**

CALENOFF ET AL.

**Examiner**

Jacob Cheu

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-16 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendment filed on 10/29/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-3, 17-19 and 21-22 are under examination. Claims 4-16 and 20 are withdrawn from further consideration.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Meola et al. (J of Immunology 1995 Vol. 45, page 3162).

Meola et al teach a using plurality of immunogenic peptides of a target protein associated with human hepatitis B virus surface antigen (HbsAg) for developing potential HbsAg vaccine (See Abstract). The selected peptides by Meola et al. have the following features: (See page 3163; Figure 1)

1. HbsAg is the target protein.
2. HbsAg sequence 120-132 is the selected peptide which is identical to a contiguous amino acid peptide region of the HbsAg (See gray overlapped area; first one).
3. Mimotope 13 and 35 are the selected immunogenic peptides as the comparative proteins from phage library.
4. Both Mimotope 13 and 35 have a net hydrophilicity nature on the cell surface.

Art Unit: 1641

5. Both Mimotope 13 and 35 have less than 50 % net homology compared to the selected HbsAg.

6. The selected HbsAg has no more than three contiguous amino acids are identical to the contiguous amino acids of the comparative Mimotope 13 and 35.

Other similar examples can also be shown if use mimotope 17 or mimotope 41 as comparative protein (See page 3163, Figure 1).

Meola et al. also teach immunizing rabbit and mice to test the immunogenic response, e.g. HbsAg antibody associated with Hepatitis B, from the fluids (serum) of the infected and control animals (See page 3164, right column, Sera assays).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1641

3. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meola et al. in view of Hasegawa et al. (US 4606857).

Meola et al. teach using recombinant technique, e.g. phage library, to synthesize peptides capable of producing immunogenicity to combat viral infection. (page 3162, Introduction) However Meola et al. do not explicitly teach coupling the selected peptides with an adjuvant molecule to enhance immunogenicity of the peptide. Hasegawa et al. teach coupling a muramyl molecule to a peptide to enhance immunogenicity reaction. (See formula I, and col. 1, line 32-42) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Meola et al. with the adjuvant molecule as taught by Hasegawa et al. to increase the efficacy of immunogenicity since it is well-known and common practice in the art to couple adjuvant molecule with the peptides for enhancement of immunogenicity.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meola et al. in view of Tu et al. (US 5674483).

Meola et al. reference has been discussed but is silent in teaching prescribing the peptide as a desensitizing agent for therapy purposes. Tu et al. teach a method of administering IL-2 in an effective amount to desensitize airway hyperactivity and subsequently prescribing IL-2 increasingly to induce immune tolerance to the specific respiratory antigens. (Col. 2, line 15-45) Tu et al. reveal that this method provides the advantages of less side effects and less toxicity. (Col. 2, line 1-10) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the peptides of Meola et al. with the desensitizing method as taught by Tu et al. in order to reduce the immune tolerance, decrease side effects and toxicity, and maximize the expected results.

***Response to Applicant's Arguments***

5. Applicant's arguments with respect to claims 1-3, 17-19 and 21-22 have been considered but are moot in view of the new ground(s) of rejection.

***Mimotopes***

6. Applicant argues that the mimotopes are not proteins or peptides derived from proteins and mimotopes cannot be defined as a comparative protein. Applicant's arguments have been considered but are not persuasive.

First of all, concerning the "comparative protein", applicant asserts that "[n]on-target proteins are selected for comparative purposes, by scanning for all available sequence matches in *computer data banks*" (See page 3, line 23-26). Furthermore, the amino acid structure of the candidate peptides are then compared to the amino acid structures found in individual "non-target, non-specific, proteins by using *computer matching program such as BLAST*" (See page 5, line 12-16). In another word, the so-called "comparative protein" can be any protein because it is a vast pool of non-target proteins as long as it is not identical to the target protein. With respect to the mimotopes, Meola et al. use recombinant technique to manufacture its related proteins in phage library. The mimotopes are not the HbsAg target proteins. The mimotopes are comparative proteins with respect to the HbsAg. Accordingly to Figure 1 of Meola et al. reference, the selection of mimtopes from the target HbsAg is clearly demonstrated with all the criteria features discussed in this Office Action (See page 3163, left column, first paragraph-"To gain more insight into the role of mimotope carrier in the induction of a specific immune response, we *decided to present selected* mimotopes on different carriers to the immune system")(emphasis added).

Art Unit: 1641

***Conclusion***

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

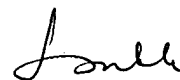
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner



Art Unit 1641

January 27, 2005



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SUPERVISORY PATENT EXAMINER  
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02/05/05